K133527

MAR - 7 2014

OSSTEM IMPLANT

Osstem Germany GmbH.

#Mergenthaler Allee 25, 65760 Eschborn, Germany
Tel. +49(0)6196 777 550 · Fax. +49 (0)6196 777 55 06
www.osstem.de, www.sinuskit.com

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: July 12, 2013

1. Company and Correspondent making the submission:

- Submitter's Name :	**Osstem Germany GmbH.**
- Address	#Mergenthaler Allee 25, 65760 Eschborn, Germany
- Contact :	Jessica Jung
- Phone:	+49 6196 777 550
- Correspondent's Name:	HIOSSEN Inc.
- Address:	85 Ben Fairless Dr. Fairless Hills, PA 19030
- Contact:	Patrick Lim
- Phone:	888 678 0001

2. Device :

Trade or (Proprietary) Name :	Suflex Impression Materials to include: Suflex putty Suflex Heavy Suflex Mono Suflex Light
Common or usual name :	Impression material
Classification Name :	Material, Impression(21 CFR 872.3660.Product) 21CFR872.3640 Class II ELW

3. Predicate Device:

Trade Name:	Panasil Impression Materials(K082560)
Trade Name:	Panasil Impression Materials(K954282)
Trade Name:	Aquasil Ultra Rigid Smart Wetting Impression Material (K021413)
Trade Name:	Aquasil Ultra XLV Smart Wetting Impression Material (K021410)
Trade Name:	Kerr VPS Impression Material(K050604)

4. Description:
Suflex Impression Materials are addition-curing, elastomeric materials with hydrophilic properties, high tear strength, dimensional accuracy, and resistance to permanent deformation. The Suflex Impression Material family consists of four different viscosities(putty, heavy, mono, light), available in an assortment of delivery systems: traditional 1:1 50ml, automix cartridge, 5:1 362ml foil bags for use in most automatic dispensing and mixing systems, and traditional 1:1 putty jars.

5. Intended use

- be placed on an impression tray(or infected directly into the mouth, depending on the technique and device)and used to reproduce the structure of a patient's teeth and gums.
- provide models for study and for production of restorative prosthetic devices.

6. Indication for use

Suflex Putty is to be used as panasil putty material for;

- Two step putty impression technique
- One step putty impression technique
- Two step putty impression technique using a foil(plastic putty spacer)
- One step putty impression technique for forming functional peripheries.

Suflex Heavy is to be used a s panasil tray material for;

- One step impressiontechnique using sinle or dual viscosities.
- Two step impression technique using dual viscosities
- Functional impressions.

Suflex Mono is to be used as panasil monophase material for;

- Taking impression over fixed/removable restorations and implants (transferring impression posts and bridge components)
- Fuctional impresssions.
- Fabricating crown and bridgework or inlays.
- Fabricating full or partical dentures.
- Reline impressions.
- Use in the simultaneous mixing technique as well as the putty
- Trnasferring root posts when fabricating posts and cores indirectly.

Suflex Light is to be used as panaasil contact material for;

- Two step putty impressiontechnique.
- One step putty impression technique.
- One step impression technique using a foil(plastic putty spacer)
- One step impression technique(simultaneous technique)using dual viscosities.
- Reline impressions.
- Fabricating full or partial dentures.

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7. Summary of Non-Clinical Performance Testing

Biocompatibility tests have been performed to assure biological safety in accordance with the ISO 10993 family. Tests in respect to cytotoxicity(ISO 10993-5), sensitization and mucosa irritation(ISO 10993-10) and a chemical analysis showed, that Suflex materials' biocompatibility data is comparable to other materials on the market.
Additionally bench testing was performed to allow an evaluation of the mechanical properties of Sulex in comparison to already marketed products. The evaluation covers

- Component colours (ISO 4823, 6.1)
- Working time (ISO 4823, 6.3)
- Compatibility with gypsum (ISO 4823, 6.4)
- Consistency(ISO 4823, 6.4)
- Detail reproduction(ISO 4823, 6.4)
- Linear dimensional change(ISO 4823, 6.4)
- Elastic recovery(ISO 4823, 6.4)
- Strain-in-compression(ISO 4823, 6.4)

The results indicate adequate consistency results compared to leading Impression materials.

8. Summary of clinical testing

No clinical studies are submitted

9. Conclusions

Osstem Germany GmbH believes that the Suflex Impression material is substantially equivalent to the currently legally marketed products. It does not introduce new indications for use, has similar technological characteristics and does not introduce new potential hazards or safety risks.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 7, 2014

Osstem Germany GmbH
C/O Mr. Patrick Lim
QA/RA Manager
HIOSSEN, Inc.
85 Ben Fairless Drive
Fairless Hills, PA 19030

Re: K133527
Trade/Device Name: Suflex Impression Materials
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: November 27, 2013
Received: December 11, 2013

Dear Mr. Lim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number K 133527

Device Name : Suflex impression materials

Indication for use :

Suflex Putty is to be used as panasil putty material for;
- Two step putty impression technique
- One step putty impression technique
- Two step putty impression technique using a foil(plastic putty spacer)
- One step putty impression technique for forming functional peripheries.

Suflex Heavy is to be used a s panasil tray material for;
- One step impression technique using single or dual viscosities.
- Two step impression technique using dual viscosities
- Functional impressions.

Suflex Mono is to be used as panasil monophase material for;
- Taking impression over fixed/removable restorations and implants (transferring impression posts and bridge components)
- Functional impressions.
- Fabricating crown and bridgework or inlays.
- Fabricating full or partial dentures.
- Reline impressions.
- Use in the simultaneous mixing technique as well as the putty
- Transferring root posts when fabricating posts and cores indirectly.

Suflex Light is to be used as panasil contact material for;
- Two step putty impression technique.
- One step putty impression technique.
- One step impression technique using a foil(plastic putty spacer)
- One step impression technique (simultaneous technique) using dual viscosities.
- Reline impressions.
- Fabricating full or partial dentures.

Prescription Use X (Per 21CFR801 Subpart D)

OR Over-The-Counter Use _____. (Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
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